

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

Product / Strength:	CURE-IT-ALL® for Injection, 50 mg/mL	Lot # / Mfg. Date:	Lot 12973 / Jan 23, 2007
Mfg. By / Site:	Generic Direct®	Packager / Site:	Generic Direct®
Batch Size:	1,000,000 vials	Packaging Date:	Jan 26, 2007
Purpose of Study:	Production Support	Study Start Date:	Jan 28, 2007
Expiration Date:	TBD	Study Duration:	36 month
Active Ingredient (API):	Aspirin	Container / Supplier:	50 cc clear vial / Fisher Scientific
API Mfg. / Lot# (s):	Sigma - Aldrich / 1234	Closure / Supplier:	Aluminum Crimp top seal / Fisher Scientific Grey Rubber Induction Seal / Fisher Scientific
Test Location(s):	Generic Pharmaceuticals, Inc., Northfield Labs		

Stability Condition / Orientation: 25°C ± 2°C/60% RH ± 5% RH

Specifications			Stability Intervals				
Test	Method	Acceptance Criteria	Initial	1 month	3 month	6 month	12 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Conforms	Conforms	Conforms	Pending Approval
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms	Pending Approval
Assay - Prolastin	TM002	90.0 to 110.0 % I.c.	100.0	99.9	99.1	98.7	Pending Approval
Moisture	TM003	NMT 2.0 %	0.9	1.1	1.2	1.3	Pending Approval
pH	TM004	6.6 to 7.4	7.0	7.1	7.1	7.0	Pending Approval
Particulate Testing - 10 µm	USP 788	NMT 6000 Counts per container	259	499	475	399	Pending Approval
Particulate Testing - 25 µm	USP 788	NMT 600 Counts per container	23	24	83	78	Pending Approval
Micro - Escherichia coli	NF001	Absent	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Absent
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Absent
Micro - Total Aerobic Count	NF001	Report Results	ND	ND	Not Tested per Protocol	Not Tested per Protocol	ND
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007	Jan 29, 2008

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

Stability Condition / Orientation: 25°C ± 2°C/60% RH ± 5% RH Inverted

Specifications			Stability Intervals				
Test	Method	Acceptance Criteria	Initial	1 month	3 month	6 month	12 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms	Conforms
Assay - Prolastin	TM002	90.0 to 110.0 % l.c.	100.0	99.8	98.6	98.7	98.2
Moisture	TM003	NMT 2.0 %	0.9	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
pH	TM004	6.6 to 7.4	7.0	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Particulate Testing - 10 µm	USP 788	NMT 6000 Counts per container	259	3100	3200	3400	3743
Particulate Testing - 25 µm	USP 788	NMT 600 Counts per container	23	390	329	324	398
Micro - Escherichia coli	NF001	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Micro - Total Aerobic Count	NF001	Report Results	ND	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007	Jan 29, 2008

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

Stability Condition / Orientation: 40°C ± 2°C/75% RH ± 5% RH

Specifications			Stability Intervals				
Test	Method	Acceptance Criteria	Initial	1 month	3 month	6 month	12 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Conforms	Conforms	Conforms	Conforms
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms	Does not conform (OOS) [1]
Assay - Prolastin	TM002	90.0 to 110.0 % l.c.	100.0	99.0	98.4	97.1	89.6 (OOS) [2]
Moisture	TM003	NMT 2.0 %	0.9	1.2	1.4	1.8	1.9
pH	TM004	6.6 to 7.4	7.0	6.8	7.3	7.3	7.3
Particulate Testing - 10 µm	USP 788	NMT 6000 Counts per container	259	378	348	456	497
Particulate Testing - 25 µm	USP 788	NMT 600 Counts per container	23	129	45	57	145
Micro - Escherichia coli	NF001	Absent	Absent	Scheduled	Not Tested per Protocol	Not Tested per Protocol	Pending Approval
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Scheduled	Not Tested per Protocol	Not Tested per Protocol	Pending Approval
Micro - Total Aerobic Count	NF001	Report Results	ND	Scheduled	Not Tested per Protocol	Not Tested per Protocol	Pending Approval
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007	Jan 29, 2008
Comments							
1	Refer to LIR number 398.01						
2	Refer to LIR number 387.00						

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

Stability Condition / Orientation: 5°C ± 3°C

Specifications			Stability Intervals			
Test	Method	Acceptance Criteria	Initial	1 month	3 month	6 month
Appearance Packaging	TM001	Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact	Conforms	Conforms	Conforms	Conforms
Appearance Reconstituted - Appearance Powder	TM001	Clear colorless solution free of visible particulate matter	Conforms	Conforms	Conforms	Conforms
Assay - Prolastin	TM002	90.0 to 110.0 % I.c.	100.0	100.1	99.9	99.7
Moisture	TM003	NMT 2.0 %	0.9	0.9	1.0	1.0
pH	TM004	6.6 to 7.4	7.0	7.0	7.0	7.1
Particulate Testing - 10 µm	USP 788	NMT 6000 Counts per container	259	123	231	103
Particulate Testing - 25 µm	USP 788	NMT 600 Counts per container	23	21	43	12
Micro - Escherichia coli	NF001	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Micro - Pseudomonas aeruginosa	NF001	Absent	Absent	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Micro - Total Aerobic Count	NF001	Report Results	ND	Not Tested per Protocol	Not Tested per Protocol	Not Tested per Protocol
Test Date(s)			Jan 29, 2007	Feb 28, 2007	Apr 28, 2007	Jul 28, 2007

Signatures:

Reviewed By _____

Approved By _____